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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,590	03/06/2001	Kurt E. Petersen	22660-0028 DIV 1	1585

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EXAMINER	
BEISNER, WILLIAM H	
ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 08/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/800,590	Applicant(s) PETERSEN ET AL.	
	Examiner William H. Beisner	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 06 March 2001 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2&3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements filed 24 July 2001 and 14 Feb. 2002 have been considered and made of record.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-5, 7-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al.(US 6,168,948) in view of Nelson et al.(US 5,770,029) and Wilding et al.(US 5,726,026).

The reference of Anderson et al. discloses a nucleic acid purification method which includes a cell lysing region (See column 6, line 44 to column 12, line 45). With respect to the solid phase binding within the lysing region, the reference discloses the use of posts (1908) and binding reagents (1912). With respect to the use of ultrasonic means in the lysing region, the reference discloses the use of ultrasonic agitation (See column 7, line 20 and Fig. 28).

With respect to claims 1-3, while the reference of Anderson et al. discloses a step of forcing a sample to flow through the lysing chamber, the reference is silent as to the relative volume of the sample with respect to the volume of the lysis chamber.

The reference of Nelson et al. discloses that it is known in the art to enrich or preconcentrate a fluid sample within a chamber that selectively retains an analyte of interest. The reference discloses that the enrichment channel places the analyte of interest in a smaller volume than the initial sample volume (See column 3, line 56, to column 4, line 12.

The reference of Wilding et al. discloses (See Figures 1 and 5), that an enrichment channel such as that disclosed by the reference of Nelson et al. can be used on a sample including cells.

In view of these teachings, it would have been obvious to one of ordinary skill in the art that the time the invention was made to enrich the cells of the primary reference using an enriching chamber construction disclosed by the reference of Wilding et al. for the known and expected result of improving detection efficiency by concentrating the sample and removing potentially interfering sample substances. This would result in the use of a volume of sample that is greater than the volume of the lysis chamber. Note, the specific volume of sample employed would have been obvious based on considerations such as the source of the sample and the concentration of analyte that is desired to be obtained from the sample source.

With respect to the claimed filter of claim 1, the binding properties of the chamber of the reference of Anderson et al. inherently imply that the chamber functions as filter. Additionally, the reference of Wilding et al. discloses the use of a filter structure (18) that can include specific binding as employed by the primary reference is known in the art. As a result, it would have been obvious to one of ordinary skill in the art to employ a filter in the chamber of the primary reference for the known and expected result of providing a means recognized in the art for enriching a channel.

With respect to the use of agitating particles or beads of claims 4, 5 and 7, the reference of Anderson et al. discloses the use of lysing particles in the chamber (See column 7, lines 1-7).

With respect to the claimed sonicating of claims 8, 10 and 12, the reference discloses the use of ultrasonic agitation (See column 7, line 20 and Fig. 28).

With respect to the use of heat in claim 9, the reference of Anderson et al. also discloses the use of heat in the lysis chamber (See column 40, lines 43-46).

With respect to the claimed sonicating during flow and/or elution, it would have been obvious to one of ordinary skill in the art to sonicate the lysing chamber during fluid flow and/or elution of analyte for the known and expected result of improving the contact of the fluid with the binding material within the lysing chamber.

6. Claims 6, 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al.(US 6,168,948) in view of Nelson et al.(US 5,770,029) and Wilding et al.(US 5,726,026) taken further in view of Henco et al.(US 5,652,141).

The combination of the references of Anderson et al., Nelson et al. and Wilding et al. has been discussed above.

Claim 6 differs by reciting that the lysing chamber includes beads for binding the analyte released from the cells.

The reference of Henco et al. discloses that it is known in the art to employ binding material in a lysing device that captures the cells to be lysed and binds the analyte released from the cells (See column 2, lines 13-45).

In view of this teachings, it would have been obvious to one of ordinary skill in the art to perform the analyte separation of the method of the modified primary reference of Anderson et al. using analyte binding material within the lysing chamber as suggested by the reference of Henco et al. for the known and expected result of providing an alternative means recognized in the art to purify the released analyte from the cells. Using the method suggested by Henco et al. eliminates the need for a separate purification chamber in the system.

With respect to claim 11, the analyte binding step suggested by Henco et al. also discloses the use of a washing step (See column 2, line 45, and column 3, lines 52-65).

With respect to claim 13, the reference of Henco et al. discloses the use of porous filters to retains the bead material within the lysing region of the device (See elements 2 and 3).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to maintain the separation beads of the modified primary reference using porous membranes as suggested by the reference of Henco et al. for the known and expected result of providing an alternative means recognized in the art to immobilize binding material within a desired reaction location. As a result, the upstream porous membrane would constitute a coarse filter while the binding material or filtration material subsequent to the upstream membrane would constitute the claimed second filter.

7. Claims 1-5, 7-10 and 12 are rejected under 35 U.S.C. 103(a) as being obvious over any of the following references: Pourahmadi et al.(US 6,440,725 or US 2002/0055167); McMillan et al.(US 2002/0039783); Petersen et al.(US 2002/0042125); McMillan et al.(US 2002/0045246) in view of Nelson et al.(US 5,770,029) and Wilding et al.(US 5,726,026).

The applied references have common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter

disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

While the instant application claims priority back to application US 09/331,911, the instant claims do not have benefit of the date of application US 09/331,911 because the subject matter of the claims is not supported by the disclosure of application US 09/331,911. Specifically, the following claimed limitations are not supported by the disclosure of application US 09/331,911: "sample forced to flow through the chamber to the volume capacity of the chamber is at least 2:1, and wherein the volume of sample forced through the chamber is at least 100microliters" (claim 1) and the limitations of claims 2, 3, 6, 11, 12 and 13. Since the instant claims 1-13 are not supported by the disclosure of application US 09/331,911, the instant claims do have benefit of application US 09/583,807 which has a filing date of 30 May 2000.

All of the references listed above have an effective filing date of 25 June 1999 and all have the same disclosures as application US 09/331,911.

These references disclose a nucleic acid purification method which includes a cell lysing region (See column 16, lines 12-53, and column 33, line 35, to column 35, line 2). With respect

to the solid phase binding within the lysing region, the reference discloses the use of solid phase filter (86) and rupturing beads (94) With respect to the use of ultrasonic means in the lysing region, the reference discloses the use of ultrasonic agitation (88).

With respect to claims 1-3, while the references discussed above disclose a step of forcing a sample to flow through the lysing chamber, the reference is silent as to the relative volume of the sample with respect to the volume of the lysis chamber.

The reference of Nelson et al. discloses that it is known in the art to enrich or preconcentrate a fluid sample within a chamber that selectively retains an analyte of interest. The reference discloses that the enrichment channel places the analyte of interest in a smaller volume than the initial sample volume (See column 3, line 56, to column 4, line 12.

The reference of Wilding et al. discloses (See Figures 1 and 5), that an enrichment channel such as that disclosed by the reference of Nelson et al. can be used on a sample including cells.

In view of these teachings, it would have been obvious to one of ordinary skill in the art that the time the invention was made to enrich the cells of the primary reference using an enriching chamber construction disclosed by the reference of Wilding et al. for the known and expected result of improving detection efficiency by concentrating the sample and removing potentially interfering sample substances. This would result in the use of a volume of sample that is greater than the volume of the lysis chamber. Note, the specific volume of sample employed would have been obvious based on considerations such as the source of the sample and the concentration of analyte that is desired to be obtained from the sample source.

With respect to the use of agitating particles or beads of claims 4, 5 and 7, the references discussed above disclose the use of lysing particles in the chamber (See column 34, line 55, to column 35, line 2).

With respect to the claimed sonicating of claims 8, 10 and 12, the references disclose the use of ultrasonic agitation (See column 33, lines 57-67).

With respect to the use of heat in claim 9, the references also disclose the use of heat in the lysis chamber (See column 16, lines 12-22).

With respect to the claimed sonicating during flow and/or elution, it would have been obvious to one of ordinary skill in the art to sonicate the lysing chamber during fluid flow and/or elution of analyte for the known and expected result of improving the contact of the fluid with the binding material within the lysing chamber.

8. Claims 6, 11 and 13 are rejected under 35 U.S.C. 103(a) as being obvious over any of the following references: Pourahmadi et al.(US 6,440,725 or US 2002/0055167); McMillan et al.(US 2002/0039783); Petersen et al.(US 2002/0042125); McMillan et al.(US 2002/0045246) in view of Nelson et al.(US 5,770,029) and Wilding et al.(US 5,726,026) taken further in view of Henco et al.(US 5,652,141).

The combination of any of the references of Pourahmadi et al.(US 6,440,725 or US 2002/0055167); McMillan et al.(US 2002/0039783); Petersen et al.(US 2002/0042125); McMillan et al.(US 2002/0045246) with Nelson et al.(US 5,770,029) and Wilding et al.(US 5,726,026) has been discussed above.

Claim 6 differs by reciting that the lysing chamber includes beads for binding the analyte released from the cells.

The reference of Henco et al. discloses that it is known in the art to employ binding material in a lysing device that captures the cells to be lysed and binds the analyte released from the cells (See column 2, lines 13-45).

In view of this teachings, it would have been obvious to one of ordinary skill in the art to perform the analyte separation of the method of the modified primary reference of Anderson et al. using analyte binding material within the lysing chamber as suggested by the reference of Henco et al. for the known and expected result of providing an alternative means recognized in the art to purify the released analyte from the cells. Using the method suggested by Henco et al. eliminates the need for a separate purification chamber in the system.

With respect to claim 11, the analyte binding step suggested by Henco et al. also discloses the use of a washing step (See column 2, line 45, and column 3, lines 52-65).

With respect to claim 13, the reference of Henco et al. discloses the use of porous filters to retains the bead material within the lysing region of the device (See elements 2 and 3).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to maintain the separation beads of the modified primary reference using porous membranes as suggested by the reference of Henco et al. for the known and expected result of providing an alternative means recognized in the art to immobilize binding material within a desired reaction location. As a result, the upstream porous membrane would constitute a coarse filter while the binding material or filtration material subsequent to the upstream membrane would constitute the claimed second filter.

9. Claims 1-5, 7-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pourahmadi et al.(WO 99/33559) in view of Nelson et al.(US 5,770,029) and Wilding et al.(US 5,726,026).

While the instant application claims priority back to application US 09/331,911, the instant claims do not have benefit of the date of application US 09/331,911 because the subject matter of the claims is not supported by the disclosure of application US 09/331,911. Specifically, the following claimed limitations are not supported by the disclosure of application US 09/331,911: "sample forced to flow through the chamber to the volume capacity of the chamber is at least 2:1, and wherein the volume of sample forced through the chamber is at least 100microliters" (claim 1) and the limitations of claims 2, 3, 6, 11, 12 and 13. Since the instant claims 1-13 are not supported by the disclosure of application US 09/331,911, the instant claims do have benefit of application US 09/583,807 which has a filing date of 30 May 2000.

The reference of Pourahmadi et al. is available as prior art under 35 USC 102(a) since the reference has a different inventive entity than the instant application and has a publication date of 08 July 1999 which is before 30 May 2000.

These references disclose a nucleic acid purification method which includes a cell lysing region (See column 16, lines 12-53, and column 33, line 35, to column 35, line 2). With respect to the solid phase binding within the lysing region, the reference discloses the use of solid phase filter (86) and rupturing beads (94) With respect to the use of ultrasonic means in the lysing region, the reference discloses the use of ultrasonic agitation (88).

With respect to claims 1-3, while the references discussed above disclose a step of forcing a sample to flow through the lysing chamber, the reference is silent as to the relative volume of the sample with respect to the volume of the lysis chamber.

The reference of Nelson et al. discloses that it is known in the art to enrich or preconcentrate a fluid sample within a chamber that selectively retains an analyte of interest. The reference discloses that the enrichment channel places the analyte of interest in a smaller volume than the initial sample volume (See column 3, line 56, to column 4, line 12.

The reference of Wilding et al. discloses (See Figures 1 and 5), that an enrichment channel such as that disclosed by the reference of Nelson et al. can be used on a sample including cells.

In view of these teachings, it would have been obvious to one of ordinary skill in the art that the time the invention was made to enrich the cells of the primary reference using an enriching chamber construction disclosed by the reference of Wilding et al. for the known and expected result of improving detection efficiency by concentrating the sample and removing potentially interfering sample substances. This would result in the use of a volume of sample that is greater than the volume of the lysis chamber. Note, the specific volume of sample employed would have been obvious based on considerations such as the source of the sample and the concentration of analyte that is desired to be obtained from the sample source.

With respect to the use of agitating particles or beads of claims 4, 5 and 7, the references discussed above disclose the use of lysing particles in the chamber (See column 34, line 55, to column 35, line 2).

With respect to the claimed sonicating of claims 8, 10 and 12, the references disclose the use of ultrasonic agitation (See column 33, lines 57-67).

With respect to the use of heat in claim 9, the references also disclose the use of heat in the lysis chamber (See column 16, lines 12-22).

With respect to the claimed sonicating during flow and/or elution, it would have been obvious to one of ordinary skill in the art to sonicate the lysing chamber during fluid flow and/or elution of analyte for the known and expected result of improving the contact of the fluid with the binding material within the lysing chamber.

10. Claims 6, 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pourahmadi et al.(WO 99/33559) in view of Nelson et al.(US 5,770,029) and Wilding et al.(US 5,726,026) taken further in view of Henco et al.(US 5,652,141).

The combination of Pourahmadi et al., Nelson et al. and Wilding et al. has been discussed above.

Claim 6 differs by reciting that the lysing chamber includes beads for binding the analyte released from the cells.

The reference of Henco et al. discloses that it is known in the art to employ binding material in a lysing device that captures the cells to be lysed and binds the analyte released from the cells (See column 2, lines 13-45).

In view of this teachings, it would have been obvious to one of ordinary skill in the art to perform the analyte separation of the method of the modified primary reference of Anderson et al. using analyte binding material within the lysing chamber as suggested by the reference of

Henco et al. for the known and expected result of providing an alternative means recognized in the art to purify the released analyte from the cells. Using the method suggested by Henco et al. eliminates the need for a separate purification chamber in the system.

With respect to claim 11, the analyte binding step suggested by Henco et al. also discloses the use of a washing step (See column 2, line 45, and column 3, lines 52-65).

With respect to claim 13, the reference of Henco et al. discloses the use of porous filters to retains the bead material within the lysing region of the device (See elements 2 and 3).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to maintain the separation beads of the modified primary reference using porous membranes as suggested by the reference of Henco et al. for the known and expected result of providing an alternative means recognized in the art to immobilize binding material within a desired reaction location. As a result, the upstream porous membrane would constitute a coarse filter while the binding material or filtration material subsequent to the upstream membrane would constitute the claimed second filter.

11. Claims 1-5, 7-10 and 12 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 10/006,848, 10/005,685, 10/006,904 and 10/006,850 which have common inventors with the instant application, in view of Nelson et al.(US 5,770,029) and Wilding et al.(US 5,726,026). Based upon the earlier effective U.S. filing date of the copending applications, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

While the instant application claims priority back to application US 09/331,911, the instant claims do not have benefit of the date of application US 09/331,911 because the subject matter of the claims is not supported by the disclosure of application US 09/331,911. Specifically, the following claimed limitations are not supported by the disclosure of application US 09/331,911: "sample forced to flow through the chamber to the volume capacity of the chamber is at least 2:1, and wherein the volume of sample forced through the chamber is at least 100microliters" (claim 1) and the limitations of claims 2, 3, 6, 11, 12 and 13. Since the instant claims 1-13 are not supported by the disclosure of application US 09/331,911, the instant claims do have benefit of application US 09/583,807 which has a filing date of 30 May 2000.

All of the applications listed above have an effective filing date of 25 June 1999 and all have the same disclosures as application US 09/331,911.

These references disclose a nucleic acid purification method which includes a cell lysing region (See column 16, lines 12-53, and column 33, line 35, to column 35, line 2). With respect

to the solid phase binding within the lysing region, the reference discloses the use of solid phase filter (86) and rupturing beads (94) With respect to the use of ultrasonic means in the lysing region, the reference discloses the use of ultrasonic agitation (88).

With respect to claims 1-3, while the references discussed above disclose a step of forcing a sample to flow through the lysing chamber, the reference is silent as to the relative volume of the sample with respect to the volume of the lysis chamber.

The reference of Nelson et al. discloses that it is known in the art to enrich or preconcentrate a fluid sample within a chamber that selectively retains an analyte of interest. The reference discloses that the enrichment channel places the analyte of interest in a smaller volume than the initial sample volume (See column 3, line 56, to column 4, line 12.

The reference of Wilding et al. discloses (See Figures 1 and 5), that an enrichment channel such as that disclosed by the reference of Nelson et al. can be used on a sample including cells.

In view of these teachings, it would have been obvious to one of ordinary skill in the art that the time the invention was made to enrich the cells of the primary reference using an enriching chamber construction disclosed by the reference of Wilding et al. for the known and expected result of improving detection efficiency by concentrating the sample and removing potentially interfering sample substances. This would result in the use of a volume of sample that is greater than the volume of the lysis chamber. Note, the specific volume of sample employed would have been obvious based on considerations such as the source of the sample and the concentration of analyte that is desired to be obtained from the sample source.

With respect to the use of agitating particles or beads of claims 4, 5 and 7, the references discussed above disclose the use of lysing particles in the chamber (See column 34, line 55, to column 35, line 2).

With respect to the claimed sonicating of claims 8, 10 and 12, the references disclose the use of ultrasonic agitation (See column 33, lines 57-67).

With respect to the use of heat in claim 9, the references also disclose the use of heat in the lysis chamber (See column 16, lines 12-22).

With respect to the claimed sonicating during flow and/or elution, it would have been obvious to one of ordinary skill in the art to sonicate the lysing chamber during fluid flow and/or elution of analyte for the known and expected result of improving the contact of the fluid with the binding material within the lysing chamber.

12. Claims 6, 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over copending Application No. 10/006,848, 10/005,685, 10/006,904 and 10/006,850 which have common inventors with the instant application, in view of Nelson et al.(US 5,770,029) and Wilding et al.(US 5,726,026) taken further in view of Henco et al.(US 5,652,141).

The combination of the copending applications with the references of Nelson et al. and Wilding et al. has been discussed above.

Claim 6 differs by reciting that the lysing chamber includes beads for binding the analyte released from the cells.

The reference of Henco et al. discloses that it is known in the art to employ binding material in a lysing device that captures the cells to be lysed and binds the analyte released from the cells (See column 2, lines 13-45).

In view of this teachings, it would have been obvious to one of ordinary skill in the art to perform the analyte separation of the method of the modified primary reference of Anderson et al. using analyte binding material within the lysing chamber as suggested by the reference of Henco et al. for the known and expected result of providing an alternative means recognized in the art to purify the released analyte from the cells. Using the method suggested by Henco et al. eliminates the need for a separate purification chamber in the system.

With respect to claim 11, the analyte binding step suggested by Henco et al. also discloses the use of a washing step (See column 2, line 45, and column 3, lines 52-65).

With respect to claim 13, the reference of Henco et al. discloses the use of porous filters to retains the bead material within the lysing region of the device (See elements 2 and 3).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to maintain the separation beads of the modified primary reference using porous membranes as suggested by the reference of Henco et al. for the known and expected result of providing an alternative means recognized in the art to immobilize binding material within a desired reaction location. As a result, the upstream porous membrane would constitute a coarse filter while the binding material or filtration material subsequent to the upstream membrane would constitute the claimed second filter.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 7-10 and 12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 54, 63, 65, 67, 77, 78, 81, 86, 87, 89, 92 , 93, 99, 104, 105, 107, 110 and 111 of copending Application No. 10/005,685. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of Application 10/005,685 encompasses the same method of lysing cells as recited in the instant claims above. With the claims of application 10/005,685 disclose forces a volume of sample through the lysing chamber that is greater than the volume of the chamber and recites a ratio of at least 2:1. With respect to the specific volume of sample employed, it would have been obvious based on considerations such as the source of the sample and the concentration of analyte that is desired to be obtained from the sample source.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 6, 11 and 13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 54, 63, 65, 67, 77, 78, 81,

86, 87, 89, 92 , 93, 99, 104, 105, 107, 110 and 111 of copending Application No. 10/005,685 in view of Henco et al.(US 5,652,141). The disclosure of claims 54, 63, 65, 67, 77, 78, 81, 86, 87, 89, 92 , 93, 99, 104, 105, 107, 110 and 111 of application No. 10/005,685 has been discussed above.

Claim 6 differs by reciting that the lysing chamber includes beads for binding the analyte released from the cells.

The reference of Henco et al. discloses that it is known in the art to employ binding material in a lysing device that captures the cells to be lysed and binds the analyte released from the cells (See column 2, lines 13-45).

In view of this teachings, it would have been obvious to one of ordinary skill in the art to perform the analyte separation of the method of the modified primary reference of Anderson et al. using analyte binding material within the lysing chamber as suggested by the reference of Henco et al. for the known and expected result of providing an alternative means recognized in the art to purify the released analyte from the cells. Using the method suggested by Henco et al. eliminates the need for a separate purification chamber in the system.

With respect to claim 11, the analyte binding step suggested by Henco et al. also discloses the use of a washing step (See column 2, line 45, and column 3, lines 52-65).

With respect to claim 13, the reference of Henco et al. discloses the use of porous filters to retains the bead material within the lysing region of the device (See elements 2 and 3).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to maintain the separation beads of the modified primary reference using porous membranes as suggested by the reference of Henco et al. for the known

and expected result of providing an alternative means recognized in the art to immobilize binding material within a desired reaction location. As a result, the upstream porous membrane would constitute a coarse filter while the binding material or filtration material subsequent to the upstream membrane would constitute the claimed second filter.

This is a provisional obviousness-type double patenting rejection.

15. Claims 1-13 are directed to an invention not patentably distinct from claims 54, 63, 65, 67, 77, 78, 81, 86, 87, 89, 92 , 93, 99, 104, 105, 107, 110 and 111 of commonly assigned application No. 10/005,685. Specifically, the claims are not patentably distinct for the same reasons as set forth in sections (13) and (14) above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 10/005,685, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

William H. Beisner
Primary Examiner
Art Unit 1744

WHB
August 11, 2003